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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,720	08/08/2001	Vincent Giguere	514012000200	4807

25226 7590 08/28/2003

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,720	GIGUERE ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a transgenic non-human animal having a knockout mutation of the EERα orphan nuclear receptor, a cell line derived from the animal and a method of making a transgenic non-human animal, classified in class 800, subclass 8, 21.

II. Claims 1-21, 28-31 and 35-38, drawn to methods of screening compounds using a transgenic non-human animal, classified in class 800, subclass 2.

III. Claims 22, 32 and 39, drawn to modulators of EERα, classified in various classes and subclasses.

IV. Claims 23-26 and 33-34, drawn to a method of modulating fat tissue growth and/or weight gain using an antibody, classified in class 424, subclass 130.1.

V. Claims 23, 24, 26 and 27, drawn to a method of modulating fat tissue growth and/or weight gain using antisense, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be used with a non-transgenic animal and the product can be used to make cells for *in vitro* assays. The method steps of Group II are distinct from those of Group I. The burden required searching the method steps of Group II with the animal, cells and method steps of Group I would be undue.

Groups I and III are patentably distinct because the animal can be used to make cells for *in vitro* assays while the modulator can be used to treat disease. The protocols and reagents for transgenics and "modulators" are materially distinct and separate. The transgenics do not require the modulators and the modulators do not require the transgenics.

Groups I and IV are patentably distinct because the animal can be used to make cells for *in vitro* assays while the method of using an antibody can be used to treat disease. The protocols and reagents for transgenics and antibody treatments are materially distinct and separate. The transgenics do not require the antibody treatment and the antibody treatment does not require the transgenics.

Groups I and V are patentably distinct because the animal can be used to make cells for *in vitro* assays while the method of using antisense can be used to treat disease. The protocols and reagents for transgenics and antisense treatments are materially distinct and separate. The transgenics do not require the antisense treatment and the antisense treatment does not require the transgenics.

Groups II and III are patentably distinct because the method of screening drugs using an animal is used to identify modulators of EERα while the modulator can be used to treat disease. A method of identifying a modulator is not a method of making the modulator or using the modulator. The protocols and reagents for methods of using transgenics to screen drugs and for using "modulators" to treat disease are materially distinct and separate. The methods do not require the modulators and the modulators do not require the methods.

Groups II and IV are patentably distinct because the method of screening compounds using an animal can be used to identify modulators of EERα while the method of using an antibody can be used to treat disease. The protocols and reagents for methods of using transgenics and antibody treatments are materially distinct and separate. The methods of using transgenics do not require the antibody treatment and the antibody treatment does not require the method of using transgenics.

Groups II and V are patentably distinct because the method of screening compounds using an animal can be used to identify modulators of EERα while the method of using antisense can be used to treat disease. The protocols and reagents for methods of using transgenics and antisense treatments are materially distinct and separate. The methods of using transgenics do not require the antisense treatment and the antisense treatment does not require the method of using transgenics.

Groups III and IV are patentably distinct because the modulators of EERα may be DNA used to produce proteins *in vitro* while the method of using an antibody can be used to treat disease. The protocols and reagents for modulators and antibody

treatments are materially distinct and separate. The modulators do not require the antibody treatment and the antibody treatment does not require the modulators.

Groups III and V are patentably distinct because the modulators of EERα may be DNA used to produce proteins *in vitro* while the method of using antisense can be used to treat disease. The protocols and reagents for modulators and antisense treatments are materially distinct and separate. The modulators do not require the antisense treatment and the antisense treatment does not require the modulators.

Groups IV and V are patentably distinct because the method of using an antibody may increase EERα expression while the method of using antisense inhibits EERα expression. The protocols and reagents for antibody and antisense treatments are materially distinct and separate. Administering antibodies does not require administering antisense and administering antisense does not require administering antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for Group I-V are different, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

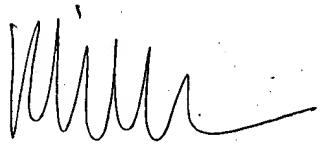
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER